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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,743	05/26/2005	Hiroyuki Osada	1261-1056PUS1	6909

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FALLS CHURCH, VA 22040-0747

EXAMINER

CHENG, KAREN

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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05/10/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/516,743	Applicant(s) OSADA ET AL.	
	Examiner Karen Cheng	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8 and 13 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-13 are currently pending in the instant application. Claims 1-3, 8 and 13 are rejected.

Response to Amendment

Applicants' amendment to the claims filed on 04/24/07 have been fully considered and entered into the application.

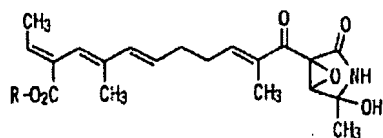
Applicants' amendments have overcome the following rejections and objections:

- The 35 USC 112 1st paragraph rejections of claim 9 has been overcome in view of applicant's cancellation of claim 9.
- The 35 USC 102(b) rejection of claims 1-3 and 8 has been overcome by amendment.
- The objection to the specification has been overcome.
- The objections to claims 5 and 9 have been overcome.

Applicants' arguments in regards to the 35 USC 103(a) rejections of claims 1-3 and 8 have been considered but are not found persuasive.

The declaration under 37 CFR 1.132 filed 04/24/07 is insufficient to overcome the rejection of claims 1-3 and 8 based upon 35 USC 103(a) as set forth in the last Office action because the objective evidence of nonobviousness is not commensurate in scope with the claims which the evidence is offered to support. In order for the prior art rejections to be overcome, the scope of the showing must be commensurate with the scope of the claims. See *In re Peterson*, 315 F.3d 1325, 1330, 65USPQ2d 1379 (Fed. Cir. 2003). Specifically the claims include a compound represented by the formula

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wherein R is a linear, branched, or cyclic alkyl having 2 or

more carbon atoms. However applicant's declaration only shows comparison of activity of the compound wherein R is methyl (linear C₁ alkyl) and t-butyl (branched C₄ alkyl).

Thus the unexpected inhibition of the growth of neuroblastoma cells has only been shown by a compound wherein R is a branched C₄ alkyl. No evidence of unexpected results for a linear alkyl with 2 or more carbon atoms (i.e. when R is an ethyl or propyl) has been shown. Applicants have failed to show that the unexpected results would occur over the entire scope of the claims, specifically when R is a linear alkyl having 2 or more carbons. Thus it cannot be determined if unexpected inhibition of the growth of neuroblastoma cells would be found with compounds in which R is a linear alkyl having 2 or more carbons or if such a result is found only when R is a branched alkyl group. The showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. In re Clemens, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980). Since the objective evidence of nonobviousness is not commensurate in scope with the claims which the evidence is offered to support, the rejections under 35 USC 103 (a) are maintained.

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

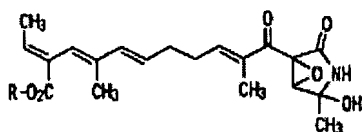
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi and Narasaka (Chemistry Letters, 1998, p. 313-314).

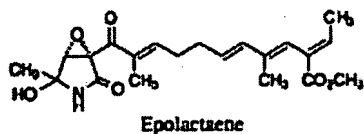
Applicants' instant elected invention in claims 1-4 and 8 teach preparation of



wherein R represents a linear, branched, or cyclic alkyl group having 2 or more carbon atoms.

Determination of the scope and content of the prior art (MPEP §2141.01)

Hayashi *et al* teach the preparation of the compound

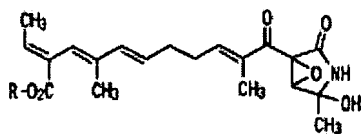


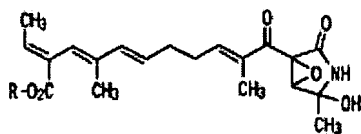
wherein R is Me.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art of Hayashi *et al* and the instantly claimed compounds of applicant is that the invention of Hayashi *et al* is directed to preparation

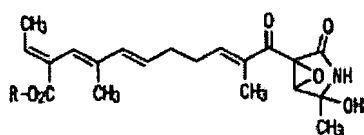
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of a compound of formula  wherein R represents methyl rather than R = linear, branched, or cyclic alkyl group having 2 or more carbon atoms claimed in the instant invention.

Finding of prima facie obviousness- rational and motivation (MPEP §2142-2143)

Hayashi *et al* is analogous art because the compounds of the structural formula



where R is an ethyl, propyl, etc would be considered analogous art. Adjacent homologues and structural isomers are generally so structurally similar that "without more" such structural similarity could give rise to prima facie obviousness. In re Wilder, 563 F.2d 457, 195 USPQ 426. For example, the substitution of a CH₃ for a H group on the -CO₂Me would lead to a CO₂Et, and in re Wood, 199 USPQ 137, hydrogen and methyl are deemed obvious variants. In the absence of unexpected results, one skilled in the art would expect that the instant claims which contain compounds that are analogous to the compounds of Hayashi *et al*, i.e. adjacent homologues of the CO₂R where R = Me, is prima facie. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. The explicit teaching of Hayashi *et al* together with the enabled examples would have motivated one skilled in the art to modify the known compounds with such generic

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teaching with the expectation that they would all have similar activity as taught by Hayashi *et al.*

Newly Added Claims Rejection - 35 USC § 103, Necessitated by Amendment

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

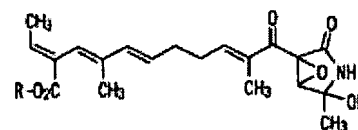
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi and Narasaka (Chemistry Letters, 1998, p. 313-314).

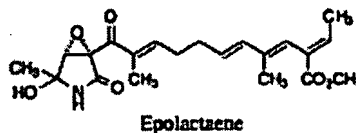
Applicants' instant elected invention in claim 13 teaches a method for inhibiting growth of neuroblastoma comprising administering an effective amount of a



pharmaceutical composition that comprises a compound of

wherein R represents a linear, branched, or cyclic alkyl group having 2 or more carbon atoms.

Determination of the scope and content of the prior art (MPEP §2141.01)



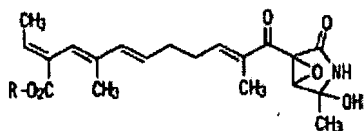
Hayashi *et al* teach that the compound is effective to the neurite outgrowth of a human neuroblastoma cell line (see column 1, paragraph 1).

Ascertainment of the different between the prior art and the claims (MPEP §2141.02)

The difference between the prior art of Hayashi *et al* and the instantly claimed compounds of applicant is that the invention of Hayashi *et al* is directed towards a method of use of the compounds wherein R represents a methyl atom rather than R = linear, branched, or cyclic alkyl group having 2 or more carbon atoms that is claimed in the instant invention.

Finding of prima facie obviousness- rational and motivation (MPEP §2142-2143)

Hayashi *et al* is analogous art because the compounds of the structural formula



wherein R is an ethyl, propyl, etc would be considered analogous art. Adjacent homologues and structural isomers are generally so structurally similar that "without more" such structural similarity could give rise to prima facie obviousness. In re Wilder, 563 F.2d 457, 195 USPQ 426. For example, the substitution of a CH₃ for a H group on the -CO₂Me would lead to a CO₂Et, and in re Wood, 199 USPQ 137, hydrogen and methyl are deemed obvious variants. In the absence of unexpected results, one skilled in the art would expect that the instant claims which contain compounds that are analogous to the compounds of Hayashi *et al*,

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i.e. adjacent homologues of the CO₂R where R = Me, is *prima facie*. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. The explicit teaching of Hayashi *et al* together with the enabled examples would have motivated one skilled in the art to modify the known compounds with such generic teaching with the expectation that they would all have similar activity as taught by Hayashi *et al*.

Claim Objections

Claim 11 is objected to because of the following informalities: cyclic is misspelled as cycloic. Appropriate correction is required.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

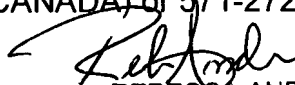
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cheng whose telephone number is 571-272-6233. The examiner can normally be reached on M-F, 9AM to 5:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Karen Cheng
Patent Examiner, AU 1626



REBECCA ANDERSON
PATENT EXAMINER

for

Joseph McKane
Supervisory Patent Examiner, AU 1626